

## **NIAMS Appeals Process**

NIH has a formal process to resolve disagreements between applicants and NIH review committees and/or NIH staff concerning the referral (assignment) and review of applications. Although procedural aspects of technical merit review are subject to appeal, differences in scientific opinion, such as may occur between applicants and reviewers, may not be contested through the NIH appeals process. Furthermore, as described below, formal appeals must be based on one or more of four specific issues and include concurrence from the authorized organization representative (AOR).

Before beginning the appeals process, the applicant is strongly advised to speak with the NIAMS program director responsible for the application. The program director can explain the options and their consequences and is often in a position to help the applicant understand the study section's recommendation. In most cases, issues can be resolved at this stage.

For those cases that cannot be resolved by discussion, the first step in the appeals process is the submission of a formal *appeal letter*. Appeal letters based solely on differences of scientific opinion will not be accepted. An appeal is a written communication from a program director/principal investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) displays concurrence from the AOR and 4) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest (COI), as specified in regulation at 42 CFR 52h.5 [PDF, 66KB] "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects," on the part of one or more peer reviewers.
- Lack of appropriate expertise within the review panel.
- Factual error(s) made by one or more reviewers that could have substantially altered the outcome
  of review.

A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter but rather a grievance, and will not necessarily be taken to Council. Appeals involving potential COI or violation of ethical conduct rules on the part of an NIH staff member or other federal

employee will be referred to the appropriate deputy ethics counselor for consideration and resolution before any further review of or action on the appeal.

An appeal letter submitted after study section review should be sent to the program director in NIAMS. The letter will be shared with the scientific review officer, who will respond in writing to the program director. Program and review staff will try to resolve the issues and take the appropriate action. If the issues cannot be resolved by staff, the appeal letter and all relevant information are made available to Council, which conducts the second level of review for research applications. **Appeals are due 3 weeks before the applicable Council** meeting. Consideration of appeals received after this date may be deferred to the following Council meeting.

The Council may agree with either the study section or the applicant. If the Council agrees with the applicant, it recommends the appropriate action to resolve the matter. If re-review is recommended, the same application, not a revised or updated version, will be re-evaluated. If the Council agrees with the study section, the applicant may decide that <u>submission of a new or revised application</u> is the best option. The program director can often give valuable advice about options.

The Council's recommendation concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process. At no time should the PD/PI or an official of the applicant organization attempt to contact individual Council members to discuss the application or appeal, as doing so could jeopardize the confidentiality and integrity of the appeals process.

An appeal of the study section or institute assignment (termed a dispute) submitted before study section review of the application should be sent to the appropriate staff in the Center for Scientific Review or the NIAMS Scientific Review Branch if the review is to be conducted by an NIAMS review committee. Referral/review staff will respond to the letter. If the response is not satisfactory, the applicant may appeal this decision following the process outlined above.